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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/025,388	12/19/2001	Ghaleb A. Sater	MIYP01-012	5072
28120	7590	09/21/2004	EXAMINER	
ROPES & GRAY LLP ONE INTERNATIONAL PLACE BOSTON, MA 02110-2624			PANTUCK, BRADFORD C	
			ART UNIT	PAPER NUMBER
			3731	
DATE MAILED: 09/21/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/025,388

Applicant(s)

SATER, GHALEB A.

Examiner

Bradford C Pantuck

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) 4-6, 10-13, 15, 16, 20 and 22-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 7-9, 14, 17-19, 21, 34-37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 12-19-01.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☒ Other: IDS 05-14-01.

## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election with traverse of claims 1-3, 7-9, 14, 15, 17-19, 21-25, 27-31, and 34-37 in the reply filed on June 28, 2004 is acknowledged. Applicant did not submit a reason for the traversal.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 4-6, 10-13, 16, 20, 26, 32 and 33 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on June 28, 2004.
3. Additionally, even though Applicant asserted in the reply filed June 28, 2004 that claims 15, 22-25, and 27-31 read on the elected Species 2 (as represented by Fig. 1C), it is *quite clear* that these claims *do not read on the elected species*. The elected species has neither a "tongue", ridges with complementary grooves, nor a hinge. Nonelected embodiment, such as Figure 1G, on the other hand, has ridges with complementary grooves and Fig. 2A has a tongue. Consequently, Claims 15, 22-25, and 27-31 have also been withdrawn from consideration.
4. Claims 1-3, 7-9, 14, 17-19, 21, and 34-37 have been examined.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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5. Claim 21 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The second member already comprises a "second engagement element" (see claim 1), so it is unclear how the first member (see claim 21) can now comprise the "second engagement element."

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 2, 3, 14, 17, 18, 21, and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,056,751 to Fenton, Jr. Regarding Claims 1 and 36, Fenton discloses a first member (26), a second member (12), and an anchor member ("barb" 52). The first member has an interior face, which is the side of the member facing second member (12). The second member has an interior face, which is (are) the side(s) facing first member (26) [see Attachment #1, Fig. 7]. The two interior faces are secured in proximity of each other, meaning that they are located close to each other [see Fig. 7]. Anchor (52) anchors/secures the surgical fastener to soft tissue [Column 4, lines 44-50].
7. Regarding Claim 2, anchor (52) is between the proximal (top of fastener in Fig. 7) and distal (bottom of fastener in Fig. 7) ends of the fastener.

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8. Regarding Claim 3, the anchors (52) are integral to the first member (26).
9. Regarding Claim 14, Fenton's fastener secures bone (48) to soft tissue (38).
10. Regarding Claims 17, 18, and 21, Fenton's Fig. 8 shows a plurality of first engaging elements/pins (54) extending distally from the interior face of first member (34) [see Fig. 9]. A plurality of second engaging elements ("bores" 50) receive the first engaging elements.
11. Claims 1-3, 7-9, 14, 19, and 34-37 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,834,752 to Van Kampen. Regarding these claims, Van Kampen discloses a surgical fastener having first member (34) and second member (32). First engagement element (threads 44) engages with second engagement element (inner surface of member 40). The interior face of first member (34) is the lower side of head (42), which faces member (32). The interior face of the second member is the upper surface of head (36), which faces member (34). Anchor members (38) have tapered heads and shanks and are connected to the exterior face (facing away from member (34) of second member (32) [Fig. 4; Column 3, lines 52-67]. Fastener secures surgical implantation device (tissue graft 10) to a bone [Column 3, lines 17-22]. It is evident from Fig. 3, because of the slot in head (42) of member (34) that a flat head screw driver is meant to drive the screw into the bone.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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12. Claims 1-3, 19, and 34-37 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,368,326 B1 to Dakin et al. Regarding Claims 1-3, 19, 36, and 37 in Fig. 6B and Column 9, lines 8-19 Dakin discloses a surgical fastener (50) having a first member (50.3/50.2) with a first interior face, which is the bottom face of the nut head (50.3) from which first engaging means (50.2) extends. Dakin discloses a second member (50.1) with an interior surface (top surface as shown in Fig. 6B) and an exterior face (bottom surface of 50.1—hidden in Fig. 6B). The surgeon uses the nut driver, i.e. “surgical implantation device” of Fig. 7 [Column 7, lines 1-4] to drive the nut through the aperture in 50.1 and into hole 54.1 in bone (54), putting interior face of bone screw (50.3/50.2) in contact with the interior face of second member (50.1). The thread of screw (50.2) acts as an anchor, anchoring the fastener to bone (54). Once the nut has been driven into the bone, the user will remove the nut driver.
13. Regarding Claims 34 and 35, Dakin’s first and second members secure “cords” 52/52.1 [Fig. 6B]. These cords are considered to be strings.

### *Conclusion*

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Patent No. 6,524,316 B1 to Nicholson et al.

U.S. Patent No. 6,200,330 B1 to Benderev et al.

U.S. Patent No. 4,060,089 to Noiles

U.S. Patent No. 6,692,507 to Pugsley

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradford C Pantuck whose telephone number is (703) 305-8621. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (703) 308-2154. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*BCP*  
BCP

September 17, 2004

*D*  
ANH TUAN T. NGUYEN  
PRIMARY EXAMINER

*9/17/04*

